
From: Max Shepherd <max.shepherd@biocellcorp.co.nz>
Sent: Tuesday, 2 June 2020 11:12 AM
To: Simon Rae
Cc: Danette Olsen; Nidish Nair
Subject: Biocell and Covid vaccine production [UNCLASSIFIED]

Hello Simon,

Danette has passed on your contact to us and as per my email below, I would be grateful if you would contact either myself on 9(2)(a) or Nidish on 9(2)(a).

Regards

Max Shepherd

From: Danette Olsen <Danette.Olsen@mbie.govt.nz>
Sent: Tuesday, 2 June 2020 7:41 AM
To: Max Shepherd <max.shepherd@biocellcorp.co.nz>; Simon Rae <Simon.Rae@mbie.govt.nz>
Cc: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: RE: Biocell and Covid vaccine production [UNCLASSIFIED]

Dear Max

I suggest you contact Simon Rae who is leading the vaccine strategy work.

Regards

Danette

From: Max Shepherd <max.shepherd@biocellcorp.co.nz>
Sent: Friday, 29 May 2020 2:24 PM
To: Danette Olsen <Danette.Olsen@mbie.govt.nz>
Cc: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: Biocell and Covid vaccine production

Hello Danette,

Max Kennedy has passed on your email as the person to contact regarding the NZ Governments Covid19 vaccine strategy implementation. Biocell has been working with an international company on a novel Covid19 vaccine and we would like to discuss Biocell's facility/capabilities and the Covid19 work with you. I would be grateful if you would call either myself or our CEO, Nidish Nair 9(2)(a).

Regards

Max Shepherd

9(2)(a)

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From: Simon Rae
Sent: Wednesday, 3 June 2020 2:55 PM
To: Danette Olsen; Max Shepherd
Cc: Nidish Nair; Michael Contaldo
Subject: RE: Biocell and Covid vaccine production [UNCLASSIFIED]

Hi Max,

Thanks for the contact – just to let you know from my end, Nidish and I had a good conversation this afternoon. We are keen to stay in touch.

Simon

From: Michael Contaldo
Sent: Wednesday, 10 June 2020 5:15 PM
To: William Rolleston
Cc: John Rolleston
Subject: RE: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

William – thanks very much indeed for coming back so quickly on this.

We will use this and come back to you with follow-up questions if we may.

Kind regards/ Michael

From: William Rolleston <william.rolleston@southpacificsera.co.nz>
Sent: Wednesday, 10 June 2020 4:00 PM
To: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Cc: John Rolleston <jr@southpacificsera.co.nz>
Subject: RE: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

Michael

Please find attached a table outlining the answers to you questions. Please let me know if you have any other questions or if you want to speak on the phone for any clarification.

Regards
 William

Dr WBR Rolleston
 Production Director, South Pacific Sera Ltd
 PO Box 2117, Washdyke, Timaru 7941
 26 Kennels Road, Timaru 7974
 New Zealand
 9(2)(a)
www.southpacificsera.co.nz

From: Michael Contaldo [<mailto:Michael.Contaldo@mbie.govt.nz>]
Sent: Wednesday, 10 June 2020 11:47 AM
To: William Rolleston
Cc: John Rolleston
Subject: RE: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

William – thanks very much for your help with this.

We're aiming to put advice to Ministers over the next few days so your responses and a follow-up call would be highly appreciated to help us better understand the domestic landscape.

Kind regards/ Michael

Michael Contaldo

Principal Policy Advisor, Innovation Policy

Mobile: 9(2)(a) ; Michael.contaldo@mbie.govt.nz

15 Stout Street, Wellington 6140 | New Zealand



From: William Rolleston <william.rolleston@southpacificsera.co.nz>
Sent: Tuesday, 9 June 2020 4:49 PM
To: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Cc: John Rolleston <jr@southpacificsera.co.nz>
Subject: RE: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

Dear Michael

John has asked me to respond to your email.

I would be very happy to have a call with you. In the meantime I will put together some bullet points to answer your questions.

Regards
William

Dr WBR Rolleston
Production Director, South Pacific Sera Ltd
PO Box 2117, Washdyke, Timaru 7941
26 Kennels Road, Timaru 7974
New Zealand
9(2)(a)
www.southpacificsera.co.nz

From: Michael Contaldo [<mailto:Michael.Contaldo@mbie.govt.nz>]
Sent: Tuesday, 9 June 2020 11:47 AM
To: John Rolleston
Subject: FW: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

Dear John,

You will have seen that the New Zealand Government recently announced its COVID-19 Vaccine Strategy. This strategy aims to secure a vaccine – safe, effective and in sufficient quantities – at the earliest possible time. It will ensure New Zealand has detailed knowledge of key international research efforts and an ability to assess promising vaccine candidates as they emerge.

A Taskforce has been set up to oversee implementation of the strategy, led by the Ministry of Business, Innovation and Employment (MBIE), along with the Ministry of Health, Medsafe, Pharmac, and MFAT. I am writing to you as part of the secretariat for that Taskforce and a policy advisor in MBIE.

One of the strands of the strategy is to develop the ability to manufacture domestically in case it is needed to secure supply. To help with this I would be interested in getting your help to answer a number of important questions which will allow us to determine current capability within the country, and what might be missing:

- Has your business been involved in producing vaccines either for use in humans or use in animals?

- If yes then what aspect of the vaccine manufacture process have you been involved in?
- Is your business licensed by government to produce (i) human vaccines and sera? (ii) animal vaccines (iii) sterile products for humans/ animal use (iv) non sterile products for human/ animal use?
- Do you have significant equipment or facilities that relate to the manufacture of vaccines – eg bioreactors? Where are the facilities located?
- How many staff does your business employ within New Zealand?
- Would you consider participating in the manufacture of a COVID-19 vaccine should one become available? If not then what main concerns are holding you back?

If it's easier then it would be great to perhaps arrange a call over the next day or two to talk this through in person?

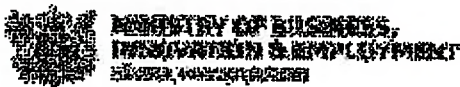
Thanks in advance for your help and kind regards,

Michael Contaldo

Principal Policy Advisor, Innovation Policy

Mobile: 9(2)(a) ; Michael.contaldo@mbie.govt.nz

15 Stout Street, Wellington 6140 | New Zealand



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1.

South Pacific Sera Ltd Responses to MBIE Vaccine Capability Questions – 10 June 2020

<p>Has your business been involved in producing vaccines either for use in humans or use in animals?</p> <p>If yes then what aspect of the vaccine manufacture process have you been involved in?</p>	<p>Yes. South Pacific Sera Ltd (SPS) produces two animal vaccines. [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
<p>Is your business licensed by government to produce:</p> <p>(i) human vaccines and sera?</p> <p>(ii) animal vaccines</p> <p>(iii) sterile products for humans/ animal use</p> <p>(iv) non sterile products for human/ animal use?</p>	<p>(i) No, however we do manufacture and supply raw materials (Donor Bovine Serum) to large multinational human vaccine manufacturers and human cytokines to development labs.</p> <p>(ii) Yes, SPS is licenced to manufacture veterinary vaccines by the Agricultural Compounds and Veterinary Medicines Group of MPI. The vaccines we manufacture are supplied into the [REDACTED] markets.</p> <p>(iii) Yes, SPS is a Medsafe approved manufacturer for sterile products for human use and by ACVM for the production of sterile products for veterinary use according to our licences.</p> <p>(iv) Yes, SPS is certified by the US FDA for production of an Active Pharmaceutical Ingredient for human use. We also supply sterile raw materials to multinational pharmaceutical companies for the production of human viral vaccines and biopharmaceuticals.</p>

<p>Do you have significant equipment or facilities that relate to the manufacture of vaccines – eg bioreactors? Where are the facilities located?</p>	<p>Yes. SPS has a manufacturing facility in Timaru, South Canterbury for the production of vaccines [redacted]. This facility is designed and constructed to PC2 requirements. [redacted] SPS has automated vial filling capability (we currently fill [redacted] in a multi dose format) as well as freeze drying (including stoppered vials) in a sterile GMP environment.</p>
<p>How many staff does your business employ within New Zealand?</p>	<p>70+</p>
<p>Would you consider participating in the manufacture of a COVID-19 vaccine should one become available? If not then what main concerns are holding you back?</p>	<p>Yes.</p> <p>SPS is currently assisting in the development of [redacted] vaccines in conjunction with research, industry and/or big pharma [redacted].</p> <p>It is hoped that should these projects lead to successful outcomes the production will be retained in New Zealand. SPS has had more than 15 years' experience in [redacted] allowing for rapid expansion of its capacity as the need arises. [redacted]</p>

From: Michael Contaldo
Sent: Friday, 12 June 2020 1:50 PM
To: Nidish Nair
Subject: RE: Biocell [UNCLASSIFIED]

Nidish – many thanks for these.

Michael

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Thursday, 11 June 2020 6:22 PM
To: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Subject: FW: Biocell [UNCLASSIFIED]

Hello Michael,

Thank you getting in touch and it was good talking to you briefly.

Please see below the answers to your questions (in blue ink).

It is also worth noting the following:

- 1) The human vaccine production facilities should be *completely separate* from animal vaccine facilities or other drug substances including animal sera preparation areas to prevent the transmission of diseases from one species to the other. This has been advised by MPI.
Please also note that to the best of our knowledge all of the vaccines being developed and manufactured around the world are regarded as devoid of any animal sourced material. FDA also has a number of guidelines recommending the same.
- 2) The viral vaccine manufacturing facility if available needs to be dedicated for viral vaccines and should be separate from other microbial processing areas.
- 3) The covid-19 vaccine manufacturing facility must have at least 2 biosafety level 2 containment clean room suites (once again dedicated).

Have a pleasant evening.

Cheers,

Nidish

From: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Sent: Monday, 8 June 2020 11:52 AM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: RE: Biocell [UNCLASSIFIED]

Hi Nidish,

Great to make a connection with you.

I was wondering whether you might have some time today/ tomorrow that I could give you a quick call? I'm especially interest in the following questions:

- Has your business been involved in producing vaccines either for use in humans or use in animals? Yes
- If yes then what aspect of the vaccine manufacture process have you been involved in? We have been involved in all aspects of vaccine production from research, formulation, trialling as well as packing, filling and product regulatory documentation.
- Is your business licensed by government to produce (i) human vaccines and sera? (ii) animal vaccines (iii) sterile products for humans/ animal use (iv) non sterile products for human/ animal use? Biocell has been a GMP approved manufacturing facility with over 30 years of experience in producing viral and bacterial vaccines and sterile injectables. The recent acquisition of ASX listed Living Cell Technology's GMP compliant cell culture facility has now enabled us to have dedicated premises for the manufacturing of COVID-19 vaccines.
- Do you have significant equipment or facilities that relate to the manufacture of vaccines – eg bioreactors? Where are the facilities located? We have dedicated equipment required for the manufacture of both bacterial and viral vaccines. In fact, to the best of our knowledge our Auckland facility houses some of the largest GMP approved pharma grade bioreactors in NZ. We also have all the other associated downstream technologies like the latest High-performance chromatography equipment (one of its kind in NZ), particle size analysers (only crown research institutes would have these), sterility testing suite in addition all the molecular and analytical equipment required for testing bacterial and viral vaccines.
- How many staff does your business employ within New Zealand? 17-20 FTEs
- Would you consider participating in the manufacture of a COVID-19 vaccine should one become available? If not then what main concerns are holding you back? Yes, we would like to participate in the manufacture of covid-19 vaccines.

Thanks in advance/ Michael

Michael Contaldo

Principal Policy Advisor, Innovation Policy

Mobile: 9(2)(a) ; Michael.contaldo@mbie.govt.nz

15 Stout Street, Wellington 6140 | New Zealand



**MINISTRY OF BUSINESS,
INNOVATION & EMPLOYMENT**
HĀKINA KAWHiriA



-----Original Message-----

From: Simon Rae <Simon.Rae@mbie.govt.nz>

Sent: Monday, 8 June 2020 10:53 AM

To: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>

Cc: Nidish Nair <nidish.nair@biocellcorp.co.nz>

Subject: RE: Biocell [UNCLASSIFIED]

Hi Michael,

Nidish is the best contact at Biocell. His number is 9(2)(a) .

Nidish,

I think when we spoke the other day I mentioned that Michael might follow up. Michael is working with me on the manufacturing part of the vaccine strategy, and is currently trying to get a broad picture of our manufacturing capacity.

I'm also interested in getting a bit more detail on your suggestion that we support some early stage manufacturing design, potentially including supporting manufacturing of trial material. We've had a few conversations towards the end of last week that suggests that might make sense for us, and I'm keen to get a bit of a sense of the costs involved so we can calibrate that against other options.

It's also worth noting that Nikolai's email that you were copied in on is not quite correct, but I'm following that up with Rod in the first instance. I was a bit cagey with Nikolai, in part because I'd prefer to deal with the New Zealand partners. Give me a call if you want more background.

Simon

Simon Rae
MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
15 Stout Street, PO Box 5762, Wellington, 6145

-----Original Message-----

From: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Sent: Monday, 8 June 2020 8:54 AM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: Biocell

Hi simon I was going to try and set up a call with someone in Biocell today. Is there anyone you recommend? Happy for me to have a chat with them to talk through their capability or would you like to be involved to?

Michael

Sent from my iPhone

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From: Michael Contaldo
Sent: Friday, 12 June 2020 3:19 PM
To: William Rolleston
Cc: John Rolleston
Subject: RE: Government's COVID-19 vaccine strategy [UNCLASSIFIED]

William,

Thanks again for providing this information.

I was wondering whether we might be able to set up a 30 minute call sometime next week so that we can follow-up with a few additional questions? At the moment any day after 4pm would work on our side (or alternatively Monday or Tuesday mornings at 11-12).

Kind regards

Michael Contaldo

Principal Policy Advisor, Innovation Policy
Mobile: 9(2)(a) [redacted]; Michael.contaldo@mbie.govt.nz
15 Stout Street, Wellington 6140 | New Zealand



**MINISTRY OF BUSINESS,
INNOVATION & EMPLOYMENT**
HĪKINA WHAKATUTUKI



From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Monday, 15 June 2020 7:00 PM
To: Simon Rae
Cc: Michael Contaldo
Subject: RE: Proposal to do production design for a vaccine candidate [IN-CONFIDENCE:RELEASE EXTERNAL]

Hello Simon,

We are still working on these questions and are hoping to send through a proposal by tomorrow.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Thursday, 11 June 2020 1:14 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Cc: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>
Subject: Proposal to do production design for a vaccine candidate [IN-CONFIDENCE:RELEASE EXTERNAL]

Nidish,

I've had a couple of discussions here about process on your proposal to do the work for Stabilitech. Our thinking is that the best process is for you to provide us with a formal proposal that we can consider.

The information we would need would be:

The project

- Description of the project. Exactly what you'd be doing, and what the project entails. High level technical information about the Stabilitech vaccine.
- Any impacts of the project on your ability to produce COVID-19 vaccines (either this, or other vaccines) beyond the life of the project
- Timeframes for the project, and also what happens once the project's complete (i.e. do you produce a standard lot and then dismantle everything, but retain the ability to stand it back up again)
- The existing project plan for the project

Ability to deliver

- A summary of key expertise within Biocell, including expertise of key staff
- External expertise you will be engaging to support the project (if any)
- Other assets (e.g. equipment) that you will be using for the project, including any new equipment you will be looking to acquire

Project Costs

- Total project costs and a high-level breakdown of those costs
- Other sources of funding for the project
- The amount you are seeking from the government

Due diligence

- A summary of Biocell's business history, and an outline of current products and services
- (I have already checked company information on the Companies Office Register, so I don't need that)
- Any due diligence information or due diligence searches you have undertaken on Stabilitech (this will allow us to undertake our own due diligence more quickly and/or add to our confidence)

The vaccine candidate

- We would like to have some information on the vaccine candidate, but I understand if this is closely held and therefore not available. Ideally, for instance, it would be good to have results of animal studies that demonstrate that it is a viable candidate, or proxies for that.

In terms of what we will be looking for it will be:

- Total cost (i.e. can we bear the total cost at this point in time given the degree of current uncertainty, current known available funding, and alternative choices for that funding)
- Alignment with the vaccine strategy as we are thinking about it at this point in time, and the extent to which it will contribute to key objectives in the strategy in the short and medium term.
- Due diligence on the parties (i.e confidence that both parties are reputable and competent and we that we have evidence to substantiate that view)

It's possible we might come back with some further questions, but I'd like to avoid having to do that. This information would be treated as commercial in confidence, and we can reasonably circumscribe its distribution. If there are things that you can only provide us under NDA that you think would be important, we can accommodate that (although it makes decision-making a bit clunkier). If you were able to provide us with this information by Monday I think we could get you a reply before the 23rd. Is that feasible?

Regards,

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145

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From: Michael Contaldo
Sent: Tuesday, 16 June 2020 11:40 AM
To: William Rolleston
Subject: COVID vaccine [UNCLASSIFIED]

Hi William – did we arrange for a zoom call this morning?

No problem if this time doesn't work – we can always do later in the week.

Regards/ Michael

Michael Contaldo

Principal Policy Advisor, Innovation Policy

Mobile: 9(2)(a) ; Michael.contaldo@mbie.govt.nz

15 Stout Street, Wellington 6140 | New Zealand



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HĪKINA WHAKATUTUKI



From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Wednesday, 17 June 2020 7:34 PM
To: Simon Rae
Cc: Max Shepherd; Deb Shepherd (deb@coalspud.co.nz)
Subject: Application to the Covid-19 Manufacturing Fund_Biocell

Hello Simon,

Thank you for your prompt response.

I have had another detailed discussion with our scientific team to evaluate the different types of vaccines that we will be able to manufacture.

1. *I can confirm that if we receive the funding, then we will be able to manufacture 5 out of the 6 categories of vaccine candidates that you have listed in your email i.e., Viral vector, protein subunit, attenuated virus, DNA and mRNA based vaccines.*
 Only minor capex additions may be required for each category depending on how the innovators set up their protocols.

This is only possible as we already have most of the associated technologies, equipment, utilities, and the scientific and technical skillset at our facility.

The only candidate that we are unable to do at this stage is the inactivated Coronavirus-based vaccine. But as you would know, there are hardly any serious vaccine contenders using this old methodology due to the weak/low immunogenic response and efficacy.

2. The bioreactors planned are of 1000L working volumes. As you know, these are the sort of volumes that are of interest to pharma companies to do technology transfer.
 The filling line we are targeting will have the ability to fill approximately 24,000 vials per hour. The filling capacity depends on the volume and the viscosity of the final product but these filling units operate at very high speeds and are not bottlenecks anymore.
3. Yes, we are only seeking support for the capital costs of the manufacturing facility. Staffing costs will be fully met by Biocell. Internally, we estimate the staffing costs to be around \$750,000. 9(2)(ba)(i)
4. 9(2)(ba)(i) You are absolutely correct, the proposal we are putting forward is leveraging the work done and investment made for Stabilitech to provide a much broader manufacturing platform to the NZ government.
5. Please note that we will be committed as a New Zealand owned contract research and manufacturing company to provide our services even after the 24-month timeframe has lapsed. At this stage, our thinking is that the 24 months would start from the time the funding is available. However, we are happy to discuss this further.

Please feel free to get in touch with me if you have any further queries.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>

Sent: Tuesday, 16 June 2020 4:08 PM

To: Nidish Nair <nidish.nair@biocellcorp.co.nz>

Cc: Max Shepherd <max.shepherd@biocellcorp.co.nz>; Deb Shepherd (deb@coalspud.co.nz) <deb@coalspud.co.nz>

Subject: RE: Application to the Covid-19 Manufacturing Fund_Biocell

Thanks Nidish,

I have a few immediate questions on a first read. I might have some further questions, but I'm going to ask these ones now, as that will potentially speed up our consideration.

You've flagged the ability to manufacture a range of vaccine candidates. It would be good to have these specified by main types, which I'd broadly categorise as follows:

- Viral vector
- Protein subunit
- Inactivated virus
- Attenuated virus
- DNA
- mRNA

I'm assuming you're looking at definitely the first one, probably the first two, but it would be good to have that confirmed.

It would be good to have a bit more precision around "sufficient volumes". I recognise that this varies depending on the specific manufacturing design, but a throughput based on the Stabilitech technology would potentially be one measure. It would also be good to know the planned capacity of the bioreactors (as this will provide a further comparator), and the capacity of the filling line (because presumably you will size the filling line for something like the upper quartile of potential outputs, and in any case this is likely to prove a hard cap on capacity for anything that requires it). Initial numbers will be OK if you are still finalising design, although I can see that we might want to specify some requirements (or a range) in a funding contract.

Part of the reason for this is that there's a distinction emerging for us between enough volume to manufacture in New Zealand vs. volumes that are commercially meaningful and that therefore make it worthwhile for larger pharma companies to do technology transfer to a contract manufacturer. We would ideally want some assurance that the facility was going to be in the latter category (although that's not necessarily black and white). I'm assuming this will also be your objective as a company too though.

Am I right in thinking that you are essentially seeking support for the full capital costs of the next stage? Am I also right in assuming that you have only included capital expenditure, and not included staffing costs, and that these will be fully met by Biocell? (I think this is fine as an approach, and I don't think I need you to estimate staff costs – I just want to be clear that we're evaluating it on the basis).

You've provided animal data for Stabilitech's Zika vaccine, which appears to provide evidence for the effectiveness of the OraPro technology, but not their COVID-19 vaccine. Can you confirm that you don't have COVID-specific data available? This is not a major issue if you don't have it, because I can see from the proposal that it is leveraging the work you've done for Stabilitech to provide a broad manufacturing platform, rather than a narrower follow-on from the Stabilitech proposal; this is somewhat contrary to my understanding when I wrote the list of questions.

The 24 month commitment of availability is very welcome, and I think I'm comfortable taking this as a starting point for a decision. Does this 24 month period start from early 2021 when the facility would become available, or would it start now? We have some doubts about the "12-18" month timeframe being discussed in the media for a vaccine;

especially as we would ideally want a vaccine that is relatively long-lasting, and this may take longer to develop. I am therefore keen to be clear about what we mean here. We will also want to ensure that we (both of us together) have a plan as to what happens after the 24 month period.

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Tuesday, 16 June 2020 1:24 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Cc: Max Shepherd <max.shepherd@biocellcorp.co.nz>; Deb Shepherd (deb@coalspud.co.nz) <deb@coalspud.co.nz>
Subject: Application to the Covid-19 Manufacturing Fund_Biocell

Hello Simon,

Thank you for giving us the opportunity to apply for the Covid19 manufacturing fund.

I would be grateful if you could give me a call or send an email confirmation that we have met your requirements for this application.

In addition to this application, I have also secured assurances from Biocell directors that if we were to receive this investment then for the next 24 months a designated facility within Biocell would be entirely dedicated to the development and manufacturing of Covid-19 vaccines to meet the needs of the NZ population.

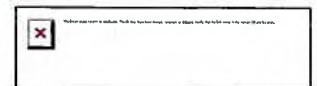
Please feel free to give me a call if you require further clarification on any aspects of the attached application.

Cheers,

Nidish

Nidish Nair
CEO

Tel +64 9 270 0755 | M 9(2)(a)
nidish.nair@biocellcorp.co.nz | www.biocellcorp.co.nz



19 Laureston Avenue, Papatoetoe, Auckland, 2025, NZ

From: Nidish Nair
Sent: Monday, 15 June 2020 7:00 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>

Cc: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>

Subject: RE: Proposal to do production design for a vaccine candidate [IN-CONFIDENCE:RELEASE EXTERNAL]

Hello Simon,

We are still working on these questions and are hoping to send through a proposal by tomorrow.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>

Sent: Thursday, 11 June 2020 1:14 PM

To: Nidish Nair <nidish.nair@biocellcorp.co.nz>

Cc: Michael Contaldo <Michael.Contaldo@mbie.govt.nz>

Subject: Proposal to do production design for a vaccine candidate [IN-CONFIDENCE:RELEASE EXTERNAL]

Nidish,

I've had a couple of discussions here about process on your proposal to do the work for Stabilitech. Our thinking is that the best process is for you to provide us with a formal proposal that we can consider.

The information we would need would be:

The project

- Description of the project. Exactly what you'd be doing, and what the project entails. High level technical information about the Stabilitech vaccine.
- Any impacts of the project on your ability to produce COVID-19 vaccines (either this, or other vaccines) beyond the life of the project
- Timeframes for the project, and also what happens once the project's complete (i.e. do you produce a standard lot and then dismantle everything, but retain the ability to stand it back up again)
- The existing project plan for the project

Ability to deliver

- A summary of key expertise within Biocell, including expertise of key staff
- External expertise you will be engaging to support the project (if any)
- Other assets (e.g. equipment) that you will be using for the project, including any new equipment you will be looking to acquire

Project Costs

- Total project costs and a high-level breakdown of those costs
- Other sources of funding for the project
- The amount you are seeking from the government

Due diligence

- A summary of Biocell's business history, and an outline of current products and services
- (I have already checked company information on the Companies Office Register, so I don't need that)
- Any due diligence information or due diligence searches you have undertaken on Stabilitech (this will allow us to undertake our own due diligence more quickly and/or add to our confidence)

The vaccine candidate

- We would like to have some information on the vaccine candidate, but I understand if this is closely held and therefore not available. Ideally, for instance, it would be good to have results of animal studies that demonstrate that it is a viable candidate, or proxies for that.

In terms of what we will be looking for it will be:

- Total cost (i.e. can we bear the total cost at this point in time given the degree of current uncertainty, current known available funding, and alternative choices for that funding)

- Alignment with the vaccine strategy as we are thinking about it at this point in time, and the extent to which it will contribute to key objectives in the strategy in the short and medium term.
- Due diligence on the parties (i.e confidence that both parties are reputable and competent and we that we have evidence to substantiate that view)

It's possible we might come back with some further questions, but I'd like to avoid having to do that. This information would be treated as commercial in confidence, and we can reasonably circumscribe its distribution. If there are things that you can only provide us under NDA that you think would be important, we can accommodate that (although it makes decision-making a bit clunkier). If you were able to provide us with this information by Monday I think we could get you a reply before the 23rd. Is that feasible?

Regards,

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
15 Stout Street, PO Box 5762, Wellington, 6145

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Application to MBIE COVID-19 Manufacturing capability fund.

Background:

Biocell Corporation is a 100% NZ owned company and has been manufacturing viral and bacterial vaccines for over 30 years at their Auckland manufacturing site.

Biocell's GMP facility has been responsible for the development and production of a number of commercialised vaccines, sterile injectables and test kits for some of the largest pharmaceutical companies, foundations/trusts, public institutions and premier universities around the world.

A recent acquisition of ASX listed Living Cell Technologies' GMP compliant cell culture facility next door has provided Biocell with a dedicated facility for the manufacturing of Covid-19 vaccines.

Biocell has already invested considerably (over \$900K) in upgrading the facility to produce vaccine material for **small scale clinical trial stage** and is now seeking government assistance through the Covid-19 Manufacturing Capability Fund to support expansion of manufacturing capability for the production of Covid-19 vaccines that would serve the needs of the NZ population and that of its immediate neighbours.

Application (PROJECT):

Biocell is seeking Government funding to further expand its manufacturing capacity and capability to support potential COVID-19 vaccine development and manufacturing. The funding would help establish manufacturing capacity for the production of a number of different Covid-19 vaccine candidates as opportunities arise as it is apparent there are significant global manufacturing and supply constraints.

If successful, the funding applied for in this application would enable Biocell's facility to manufacture sufficient volumes of COVID-19 vaccines to serve the needs of the NZ population and later its immediate neighbours. Of the 100 odd vaccine candidates currently in various trials, **this facility will have the ability and capacity to initiate technology transfer and then manufacture the front running vaccine candidates. This is due to the similarity of technology used (the sub-unit vector based strategy) in these vaccines.**

Additionally, this investment would future-proof NZ's capacity to partner in the ongoing research and development and subsequent manufacture of other life-saving vaccines which are being developed by both international and NZ researchers amidst the increased risk of further pandemics.

Having a NZ-owned facility of this nature will greatly contribute to NZ's pandemic preparedness plans as scientists have already highlighted the likelihood of a pandemic striking the human population every 10 years or so.

Currently, Biocell is working with Stabilitech (a U. K based biotechnology company) on their Covid-19 vaccine project, 9(2)(ba)(i)

High level technical information about the Stabilitech vaccine.

- Any impacts of the project on your ability to produce COVID-19 vaccines (either this, or other vaccines) beyond the life of the project
- Timeframes for the project, and also what happens once the project's complete (i.e. do you produce a standard lot and then dismantle everything, but retain the ability to stand it back up again)
- The existing project plan for the project

Biocell will be producing Stabilitech's Covid-19 vaccine for clinical trials that are set to begin in the U.K in August 2020. Stabilitech's vaccine follows a similar approach to the one the Oxford team of researchers have developed but has the added advantage of not requiring cold chain for transport and storage. This proprietary technology enables the vaccine to be administered orally. If successful, this would contribute greatly to the vaccine being available to developing as well as developed countries.

The timeframe for the Stabilitech Covid-19 vaccine project, for which we have reconfigured the facility is 2 months. Rigorous and extensive validations, qualifications, biosafety compliance, new equipment, technology adaptations and personnel training were undertaken to have the facility ready to produce vaccine material for small scale clinical trial stage.

Beyond the life of Stabilitech project and what happens once this is complete

9(2)(ba)(i)

Biocell has already invested considerably in making the facility ready to produce vaccine material to the clinical trial stage (over \$900K) however, we are not in a position to produce commercial quantities of human vaccines.

In order for manufacturing to occur in for example in early 2021 when a vaccine candidate might become available, we would require the funding immediately to carry out the installation, operational and process qualification to pharmaceutical standard which requires to happen several months in advance.

In addition, there is an increased uncertainty around the lead times required for acquiring the specialised manufacturing equipment globally. These are some of the reasons that early funding is required.

If we are to receive this investment, the Biocell directors will give assurance to the NZ government that for the next 24 months a designated facility within Biocell would be entirely dedicated to the development and manufacturing of Covid-19 vaccines to meet the needs of the NZ population.

Going forward, the government will have confidence that there is both research and development capability along with manufacturing capacity to support future vaccines as part of NZ's pandemic preparedness planning.

Ability to deliver

Biocell has been operating a GMP facility for over 30 years and houses all the significant utilities, highly trained scientific and technical professionals and infrastructure required for the production of vaccines which would require a significant amount of capital, years of validations, planning, safety and regulatory compliance to set up and maintain.

Biocell scientists have together **published more than 100 original articles** in international scientific journals and contributed to numerous books and reviews and have around **20 patents** under their names.

Biocell's GMP-compliant pharmaceutical facility already operates key downstream instruments such as : 9(2)(ba)(i)

[REDACTED]

Along with the physical infrastructure and the technical equipment to support and fast track this research, Biocell has a team of molecular, analytical, formulation, product development and cell culture scientists, virologist, technologists, engineers and Quality Assurance and Quality Control professionals.

Biocell has a robust supply chain in place 9(2)(ba)(i)

[REDACTED]

Biocell has ongoing research contracts with the University of Otago, the University of Auckland and Massey University. Researchers from these universities have and are currently working with Biocell personnel on various projects.

Biocell's collaboration with the University of Otago's Free Radical Research group led by Rutherford medal awardee Dr. Christsine Winterbourne led to the successful commercialisation of a diagnostic test kit which has now become the gold standard in the industry working on free radical groups and its effects on ageing and various diseases. In addition to university collaborations, Biocell has industry contacts and contracts with several global pharmaceutical companies.

Project Costs

- Total project costs and a high-level breakdown of those costs
- Other sources of funding for the project
- The amount you are seeking from the government

Biocell has already invested over \$900,000 in making the facility ready to produce Covid-19 vaccine material to the clinical trial stage.

We are now seeking a sum of \$2.88 million dollars to support expansion of manufacturing capability for the production of **any of the top 80% of the front running Covid-19 vaccine candidates** that would serve the needs of the NZ population and that of its immediate neighbours.

A high-level breakdown:

- Scientific and safety consumables: 9(2)(b)(ii)
 - Dedicated steriliser: 9(2)(b)(ii)
 - Cell reactors: 9(2)(b)(ii)
 - Filling line: 9(2)(b)(ii)
 - Steam in place and clean in place Centrifuge: 9(2)(b)(ii)
- TOTAL: \$2,880,000

Due diligence

Commercial due diligence, Stabilitech

Stabilitech successfully closed a recent fund-raising round and is primarily funded by private investors and the UK Department of Health through Innovate U.K.

Stabilitech has worked with esteemed organisations like US Department of Defense, Zoetis, GlaxoSmithKline (GSK) and has developed the world's first oral Zika vaccine.

The vaccine candidate

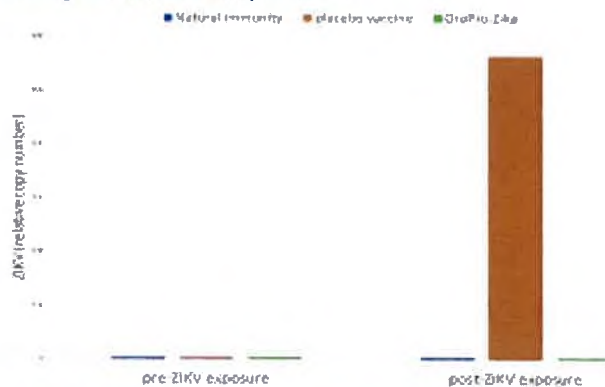
- We would like to have some information on the vaccine candidate, but I understand if this is closely held and therefore not available. Ideally, for instance, it would be good to have results of animal studies that demonstrate that it is a viable candidate, or proxies for that.

Stabilitech vaccine platform proof of concept:

The proof of approach for OraPro-COVID-19 has already been completed with the development of an oral vaccine for Zika, OraPro-Zika™, funded by the UK Department of Health through Innovate UK. OraPro-Zika has been shown to elicit protective efficacy in both mice and non-human primates in response to the wild type Zika virus. The vaccine delivers a payload of Zika antigen-expressing DNA to the cells of the intestinal lumen, resulting in the expression of the protective antigenic protein and an effective immune response.

Non-human primate challenge

OraPro-Zika was manufactured in the UK and shipped (without a cold chain) to Brazil for pre-clinical testing in non-human primates.



Subjects were tested and confirmed Zika negative before commencing the programme (pre-OraPro-Zika vaccine). 21 days after vaccination (or placebo), an aggressive live Zika challenge was administered intravenously and the subsequent Zika infection was recorded (post-ZIKV exposure). The 'post-ZIKV exposure' results clearly show that the immunity gained from OraPro-Zika appears as effective at halting a Zika virus infection as the natural immunity of subjects who have previously been infected with a whole Zika virus.

Conclusion:

BioCell has invested significant time, resources and capital in getting a dedicated facility compliant to manufacture GMP compliant small-scale clinical trial material for a Covid-19 vaccine. We are now uniquely placed to work with other vaccine developers to support their R and D efforts as well as contract manufacture.

This is now a great opportunity for the NZ government through its manufacturing fund to support a local NZ owned company that is looking to make available a world class facility available to NZ and the international scientific community to produce at scale human vaccines including a number of Covid-19 vaccine candidates.

Most importantly this investment provides a facility that gives confidence to the NZ government that it has access to development and manufacturing capacity to support future vaccines as part of NZ's pandemic preparedness planning.

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Tuesday, 23 June 2020 9:07 PM
To: Simon Rae
Subject: Re: Application for funds to support COVID-19 vaccine manufacturing [IN-CONFIDENCE:RELEASE EXTERNAL]

Hello Simon,

Thank you very much for this written approval of our proposal in principle.

We can now confidently factor this into our decision making process.

It was a pleasure dealing with you in this process and I very much valued your guidance and support along the way.

Cheers,
 Nidish

Sent from my iPhone

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Tuesday, June 23, 2020 6:11 PM
To: Nidish Nair
Subject: Application for funds to support COVID-19 vaccine manufacturing [IN-CONFIDENCE:RELEASE EXTERNAL]

Nidish,

I will send you a formally signed letter over the next day or so, but this is to provide notice in writing MBIE has decided to approve in principle support for BioCell’s proposal to develop its capability to undertake COVID-19 vaccine manufacturing at the level requested (\$2.88m).

We will have a few requirements that we will need to work through in contracting. The most significant ones are:

1. We would like to structure the contract as the purchase of a manufacturing option for five years. I recognise this is longer than the 24 months offered in the proposal, but I am hopeful that this will come down to how the option is structured, because we recognise that we will need to accommodate your commercial model and your need to be able to take on other commercial contracts which may involve a different manufacturing set up. I think the trick will be about how we specify what the option entails. We will also want to ensure that it is not seen as an impediment to you obtaining COVID-19 vaccine manufacturing contracts (as that would be contrary to our own aims).
2. We recognise that to execute we will need to provide the funding up front, but equally we will need to ensure we have provisions in place to protect ourselves in the event you are not able to provide the capability required. This will require some clawback provisions in the funding contract.

I hope these two conditions are not seen as overly onerous, but give me a call tomorrow if you want to talk through their implications a bit more.

In addition to the support for manufacturing we would be keen to work with you to support technology transfer to the BioCell to enable COVID-19 vaccine manufacturing in practice. We’ve identified this as potentially one of the key challenges in ensuring sufficient global supply of COVID-19 vaccines, and we have been looking at opportunities to support this as a way for the international community to support rapid scale up of manufacturing capacity in a way that can respond to different vaccine candidates as these emerge. Our assumption is that this sort of approach will support your commercial interests, as well as New Zealand’s own national need for access to a vaccine.

I personally am really excited by the opportunity to work with you on this, and I think this capability has the potential to make a really significant difference to how we respond to the COVID-19 pandemic.

Regards,

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145

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From: Simon Rae
Sent: Monday, 29 June 2020 5:09 PM
To: Nidish Nair
Cc: Danette Olsen; Michael Contaldo
Subject: Letter in response to manufacturing proposal [IN-CONFIDENCE:RELEASE EXTERNAL]
Attachments: Response letter to BioCell on manufacturing proposal.doc

Nidish,

As discussed, attached is a letter providing you with formal advice of our in-principle approval of your request for support for manufacturing capability. Once you've had a chance to discuss this with your Board it would be good to get together and work out next steps.

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145

29 June 2020

Nidish Nair
CEO, BioCell Corporation
PO Box 23610
Hunters Corner
Manakau City 2155
New Zealand

Dear Nidish,

Request for support for COVID-19 vaccine manufacturing capability in New Zealand

I refer to your emails of 16 June and 17 June requesting \$2,880,000 to support BioCell to develop its capacity to manufacture COVID-19 vaccines.

I am pleased to be able to let you know that MBIE has decided to support this proposal in principle, subject to us being able to reach agreement on suitable contractual arrangements. Subject to the outcome of these negotiations, our intention is that a contractual arrangement would be framed around:

- MBIE purchasing an option for BioCell to manufacture COVID-19 vaccines for a period of five years
- The contract would specify the scope of this option in terms of the types and volumes of vaccines the facility would be able to manufacture within the scope of this contract
- Funds would be provided in a single, up-front purchase to allow BioCell to make the necessary capital investments, but would include provisions for repayment of funds if BioCell is unable to fulfil its obligations to provide the manufacturing capability described.

If this outline is broadly acceptable to BioCell, I would suggest that as a next step we arrange a meeting, either face-to-face or via video-conference to discuss in greater detail how the contractual relationship might work in practice, prior to us providing a draft contract. I am conscious that there is significant complexity in how a manufacturing relationship, probably with a third party providing technology transfer, is likely to work in practice, and that there are also a number of unknowns that we will need to account for.

I look forward to discussing this with you further.

Yours sincerely,



Simon Rae
Manager International Science Partnerships
Science Innovation and International Branch
Labour Science and Enterprise Group





From: Simon Rae
Sent: Friday, 3 July 2020 4:52 PM
To: Nidish Nair
Subject: Update on timelines [UNCLASSIFIED]

Nidish,

Just a quick email before I go on leave for a week. We are aiming to get you a draft contract by the end of the week I get back (17 July).

Simon

Simon Rae
MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
15 Stout Street, PO Box 5762, Wellington, 6145

From: Simon Rae
Sent: Thursday, 16 July 2020 4:46 PM
To: Nidish Nair
Cc: Karen McDonald
Subject: Visit to Auckland [UNCLASSIFIED]

Hi Nidish,

Peter Crabtree (vaccine taskforce chair) and I will be in Auckland on 28 July, and we'd really like to meet with you and see your facilities. Would you be available? (We have quite broad availability in terms of times at the moment).

I've copied in Peter's EA Karen, who has oversight of our plans for Auckland and will be able to organise specific arrangements.

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: +9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Thursday, 23 July 2020 12:58 AM
To: Simon Rae
Subject: RE: Apology [UNCLASSIFIED]

Thank you, Simon. We look forward to receiving it.

Once all the equipment is in place and has been validated and if the technology transfer goes to plan, we can begin production in a few months.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Wednesday, 22 July 2020 9:52 AM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: RE: Apology [UNCLASSIFIED]

No, feel free to bother me about that – I'm not happy that we haven't got it to you yet. I'm keen to have this to you today, tomorrow at the latest.

BTW, I'm likely to be asked later this week. Assuming we could get a license and technology transfer, and other things go to plan, what is the earliest you think you would be able to be producing doses of a viral vector vaccine?

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Tuesday, 21 July 2020 5:58 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: Apology [UNCLASSIFIED]

Hello Simon,

I trust you have had a pleasant weekend.

Sorry to bother you, I had a directors call today and got asked about this contract, would you please be able to give us an update?

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Friday, 17 July 2020 5:33 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: Apology [UNCLASSIFIED]

Nidish,

Unfortunately my lawyers have not got back to me on the draft contract in time for me to send it to you today. I will have to chase them on Monday, and see where they have got to.

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
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From: Simon Rae
Sent: Tuesday, 18 August 2020 12:21 PM
To: Nidish Nair
Subject: RE: Vaccine Strategy - Woods PR - v2 [UNCLASSIFIED]

Thanks Nidish for the speedy turnaround.

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Tuesday, 18 August 2020 12:16 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: Vaccine Strategy - Woods PR - v2

Thank you for sharing this draft, Simon.

This is very well written.

I can confirm that we are comfortable with this press release.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Tuesday, 18 August 2020 11:40 AM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: Fwd: Vaccine Strategy - Woods PR - v2

Sorry Nidish, this got jammed in our firewall.

Simon Rae
 Manager International Science Partnerships
 Science, Innovation and International Policy
 Ministry of Business, Innovation and Employment

simon.rae@mbie.govt.nz | 9(2)(a) 
 15 Stout Street, PO Box 5762, Wellington, 6145

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Tuesday, August 18, 2020 11:04 AM
To: Nidish Nair
Cc: Stephanie Symynuk
Subject: FW: Vaccine Strategy - Woods PR - v2

Nidish,

As discussed our draft PR. Let us know if you have any issues. It is due with our Minister's office at midday, but we may have a little leeway.

Simon

Simon Rae

MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
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Hon Megan Woods

Minister of Research, Science and Innovation

DRAFT MEDIA STATEMENT

XX August 2020

Progress for the COVID-19 vaccine strategy

The Government has made significant steps towards their mission to ensure that New Zealand has access to a safe and effective COVID-19 vaccine through important international contributions and domestic research and manufacturing capability investments, Research, Science and Innovation Minister Megan Woods announced today.

“The national COVID-19 Vaccine Strategy ensures that we are pursuing a number of different avenues in order to obtain a vaccine at the earliest possible time, if and when a safe and effective vaccine is developed” said Megan Woods.

“The Government has allocated additional funding from the COVID Response and Recovery Fund to advance the COVID-19 Vaccine Strategy, on top of the \$37 million we have already set aside. A critical objective of these additional funds is to enable the government to secure access to promising vaccine candidates, in addition to joining initiatives such as the global COVAX Facility.

“Governments around the world are using purchasing arrangements to secure supply, and this will be a key mechanism for helping New Zealand to gain access to COVID-19 vaccines. Our approach to obtaining a COVID-19 vaccine is different to how we’d usually operate, but these are extraordinary times that warrant new and innovative approaches being used. We need to act early to secure our ability to purchase promising vaccine candidates and are already in conversation with a number of vaccine providers.

“We will continue our contributions to the global effort to prioritise the development and equitable distribution of COVID-19 vaccines. New Zealand has joined CEPI (the Coalition for Epidemic Preparedness Innovations) Investors’ Council with an initial investment of \$15 million towards global research efforts.

The Government is also investing in local vaccine research and manufacturing capability.

“Vaccine Alliance Aotearoa New Zealand – Ohu Kaupare Huaketo will receive \$10 million to lead COVID-19 vaccine research and will establish a vaccine development and evaluation platform. This platform will support the development of potential domestic and international COVID-19 vaccines by evaluating the safety and efficacy of vaccine candidates.

“We are also investing in local manufacturing, which may provide us with the ability to contribute to global supply. Biocell will receive \$3 million to upgrade existing facilities so that

it has the necessary scale to support global vaccine supply. This also provides the potential for New Zealand to manufacture COVID-19 vaccines locally.”

The investments in CEPI, Vaccine Alliance Aotearoa New Zealand – Ohu Kaipare Huaketo and Biocell are part of the initial **\$37 million allocation** which was announced in May for the national **COVID-19 Vaccine Strategy**.

“The government is working hard to ensure that New Zealanders have access to a safe and effective vaccine at the earliest possible time, and that we can support our Pacific neighbours to access a vaccine, too. Global cooperation is crucial because as long as one country or community is at risk, we are all at risk,” said Megan Woods.

Media contact: XXXXX

NOTE FOR EDITORS:

Vaccine Alliance Aotearoa – Ohu Kaipare Huaketo New Zealand is a partnership between the Malaghan Institute of Medical Research, the University of Otago and Victoria University of Wellington which brings together a multidisciplinary team of local and international collaborators with proven capability in vaccine research, development, and scale-up manufacturing.

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Friday, 21 August 2020 12:41 PM
To: Simon Rae
Subject: RE: Update on media announcements [UNCLASSIFIED]

Thank you for the update, Simon.

From our end:

9(2)(ba)(i)

I am at my desk all day if you wish to discuss anything further.

Cheers,

Nidish

From: Simon Rae <Simon.Rae@mbie.govt.nz>
Sent: Friday, 21 August 2020 10:34 AM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: Update on media announcements [UNCLASSIFIED]

Kia ora Nidish,

Following on from my conversation with you earlier in the week there has been some discussion with our Minister's office and the Prime Minister's office about announcements. It is now looking likely that there will be two separate announcements – one (potentially today) on our engagement with pharmaceutical companies, and then a separate announcement next week with an event at the Malaghan Institute announcing our investments in the research platform, our contribution to CEPI, and our investment with Biocell. I will let you know for sure once we get a read out from the Minister's office, but there is a bit of a risk that it may happen very quickly.

9(2)(ba)(i)

Simon

Simon Rae
MANAGER, INTERNATIONAL SCIENCE PARTNERSHIPS

Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
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From: Ros Stanley <ros.stanley@biocellcorp.co.nz>
Sent: Wednesday, 26 August 2020 3:53 PM
To: Zachary Clarke
Subject: RE: For review - Draft MBIE/BioCell contract

Really appreciate your prompt reply Zach.
Have a good rest of the day.

Thanks
Roz

From: Zachary Clarke [mailto:Zachary.Clarke@mbie.govt.nz]
Sent: 26 August, 2020 3:48 PM
To: Ros Stanley
Subject: RE: For review - Draft MBIE/BioCell contract

Hi Ros,

No worries, cashflow's always worth getting right!

Payment will come through sometime next week. I'm hoping we'll be able to manage Monday the 31st, but it may be Wednesday or Thursday if there are any issues with our payment system. I'll keep you posted if there are any updates.

Cheers,
Zach

Zachary Clarke

Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)

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INNOVATION & EMPLOYMENT**
HIKINA WHAKATUTUKI



From: Ros Stanley [mailto:ros.stanley@biocellcorp.co.nz]
Sent: Wednesday, 26 August 2020 3:43 p.m.
To: Zachary Clarke
Subject: FW: For review - Draft MBIE/BioCell contract

Hi Zachary

Trust you are enjoying that lovely sun out there amongst all the doom and gloom.

Sorry to be a pain was wondering whether you would be able to quote an approximate date of when we could expect payment please.

In the process of preparing cashflow forecasting and trying to fill in the blanks!

Many thanks

Regards
Roz

From: Ros Stanley
Sent: 20 August, 2020 1:07 PM
To: Zachary Clarke (Zachary.Clarke@mbie.govt.nz)
Subject: FW: For review - Draft MBIE/BioCell contract
Importance: High

Hi Zachary
Managed to get that screenshot after all!

Thanks
Roz

Rosalind Stanley
Administration and Accounts Manager

Tel +64 9 2594136
ros.stanley@biocellcorp.co.nz | www.biocellcorp.co.nz



19 Laureston Avenue, Papatoetoe
PO Box 23-610
Hunters Corner, Auckland 2155, New Zealand

From: Ros Stanley
Sent: 20 August, 2020 12:53 PM
To: Zachary Clarke
Cc: Simon Rae; Nidish Nair
Subject: RE: For review - Draft MBIE/BioCell contract
Importance: High

Hi Zachary
Bank account statement with requested details.

Regards

Rosalind Stanley
Administration
Tel +64 9 2594136
ros.stanley@biocellcorp.co.nz | www.biocellcorp.co.nz



19 Laureston Avenue, Papatoetoe
PO Box 23-610

Hunters Corner, Auckland 2155, New Zealand

From: Nidish Nair
Sent: 20 August, 2020 12:30 PM
To: Zachary Clarke
Cc: Simon Rae; Ros Stanley
Subject: RE: For review - Draft MBIE/BioCell contract

Kia ora Zachary,

Thank you for sending through the countersigned contract.

Ros, would you please provide Zachary with the requested account verification details.

Simon and Zachary, we really appreciate the way you have promptly executed this agreement amidst the increasing workload at the Ministry.

Cheers,

Nidish

From: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Sent: Wednesday, 19 August 2020 6:13 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Cc: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: For review - Draft MBIE/BioCell contract

Kia ora Nidish,

Please see attached for the countersigned contract. We should now be good to go, and I'll get the payment process started on our end tomorrow.

To facilitate this process, we'll need to set BioCell up as a supplier in our system. Could you please send me third party verification of your preferred bank account (such as a screenshot or photo of the account in internet banking)? This is required by our Finance team to ensure that we don't pay the wrong account because of human error, and the verification will need to show the name of the bank, the name of the account, and the account number itself (anything else can be redacted if confidential).

Ngā mihi nui,
Zachary

Zachary Clarke

Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)

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From: Nidish Nair [<mailto:nidish.nair@biocellcorp.co.nz>]
Sent: Thursday, 13 August 2020 5:30 p.m.
To: Zachary Clarke
Cc: Simon Rae
Subject: RE: For review - Draft MBIE/BioCell contract

Thank you for the prompt update, Zachary.

Cheers,

Nidish

From: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Sent: Thursday, 13 August 2020 5:02 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Cc: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: For review - Draft MBIE/BioCell contract

Hi Nidish,

We're aiming to get the signed agreement to you tomorrow, but it may end up being Monday next week. The fund we're using (SSIF) requires written approval from our Deputy Chief Executive before we can sign the contract, which may be delayed slightly due to the resurgence of COVID-19.

Cheers,
Zachary

Zachary Clarke

Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)

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From: Nidish Nair [<mailto:nidish.nair@biocellcorp.co.nz>]
Sent: Thursday, 13 August 2020 4:50 p.m.
To: Zachary Clarke
Cc: Simon Rae
Subject: RE: For review - Draft MBIE/BioCell contract

Hello Zachary,

A quick note to check if we can expect the executed agreement by the end of this week.

Cheers,

Nidish

From: Nidish Nair
Sent: Tuesday, 11 August 2020 2:13 PM
To: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Cc: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: For review - Draft MBIE/BioCell contract

Kia ora Zachary,

Thank you for promptly confirming the acceptance of our edits.

I have accepted all your drafting edits and have attached a signed copy of the agreement for execution at your end.

Please return a copy of the executed agreement for our records.

Cheers,

Nidish

Nidish Nair
CEO

Tel +64 9 270 0755 | M 9(2)(a)
nidish.nair@biocellcorp.co.nz | www.biocellcorp.co.nz



19 Laureston Avenue, Papatoetoe, Auckland, 2025, NZ

From: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Sent: Tuesday, 11 August 2020 11:19 AM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Cc: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: For review - Draft MBIE/BioCell contract

Kia ora Nidish,

Our Finance team has confirmed that we'd have no issues with the addition of the Income Tax Act clause, so we're now good to go on the contract. If your team doesn't have any further changes, we'll be able to countersign the revised contract once we receive a signed copy from you.

Ngā mihi nui,
Zachary

Zachary Clarke
Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)

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**MINISTRY OF BUSINESS,
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From: Zachary Clarke
Sent: Friday, 7 August 2020 4:50 p.m.
To: Nidish Nair
Cc: Simon Rae; Elizabeth Rose; Emma Wharam
Subject: RE: For review - Draft MBIE/BioCell contract

Kia ora Nidish

We've accepted all the major changes, and have revised the contract (see the track changes in the attached) with a few minor drafting edits from our legal team in line with MBIE's standard practice. Please let me know if your team has any questions about those changes.

One thing to note is that while we're instinctively comfortable with the addition of the Income Tax Act text in clause 3, schedule 1 (highlighted in the attached), we need to confirm with our finance team that there would be no issues from including it in the contract. We're expecting to receive confirmation from them on Monday next week, after which we'll be able to countersign the contract.

Thanks again for your work on this Nidish, and I hope you have a great weekend!

Ngā mihi nui,
Zachary

Zachary Clarke

Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)

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HIKINA WHAKATUTUKI



From: Nidish Nair [<mailto:nidish.nair@biocellcorp.co.nz>]
Sent: Monday, 3 August 2020 5:21 p.m.
To: Zachary Clarke
Cc: Simon Rae; Elizabeth Rose; Emma Wharam
Subject: RE: For review - Draft MBIE/BioCell contract

Hello Simon and Zachary,

Simon, it was an absolute pleasure meeting you and Peter last week.

The way you and the team ran our pandemic response amidst the unsettling global uncertainty is commendable and has been great for New Zealand.

We are eager to quickly move forward with this project and have only made minor changes to the contract to capture some of the uncertainties around supply chains that we discussed in our meeting.

I have attached a signed copy of the edited contract for you to countersign. A word file showing all changes compared to the version that you provided is also attached if you wish to discuss or make any changes prior to execution.

Please feel free to give me a call or email me if you wish to discuss anything further.

We look forward to working with you and the team on this project.

Cheers,

Nidish

Nidish Nair
CEO

Tel +64 9 270 0755 | M 9(2)(a) [REDACTED]
nidish.nair@biocellcorp.co.nz | www.biocellcorp.co.nz



19 Laureston Avenue, Papatoetoe, Auckland, 2025, NZ

From: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Sent: Thursday, 23 July 2020 3:54 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Cc: Simon Rae <Simon.Rae@mbie.govt.nz>; Elizabeth Rose <Elizabeth.Rose@mbie.govt.nz>; Emma Wharam <Emma.Wharam@mbie.govt.nz>
Subject: For review - Draft MBIE/BioCell contract

Kia ora Nidish

See attached for the draft contract for our planned investment with BioCell for your review. Please send through an updated version in track changes if your team would like any updates to the contract. We'll then arrange a time to discuss, or accept them and send out a final version for signing.

Ngā mihi nui,
Zachary

Zachary Clarke
Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a) [REDACTED]

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FUNDING AGREEMENT
FOR
COVID-19 VACCINE MANUFACTURING CAPACITY AND CAPABILITY

DATED the day of 2020

BETWEEN The Sovereign in Right of New Zealand acting by and through the Chief Executive of the Ministry of Business, Innovation and Employment (or by his or her authorised delegate) ("Ministry")

AND Biocell Corporation Limited of 19 Laureston Avenue, Papatoetoe, Auckland, 2025, New Zealand, company number 163505 ("Recipient")


BACKGROUND

The Ministry wishes to contribute to the Project by providing funding from the appropriation set out in the Details on the terms set out in this Agreement.

AGREEMENT

The Ministry will pay the Funding to the Recipient, and the Recipient accepts the Funding, on the terms and conditions set out in Schedule 1 (Details) and Schedule 2 (Funding Agreement Standard Terms and Conditions) (together the "Agreement").

Signed by the Sovereign in Right of New Zealand acting by and through the Chief Executive of the Ministry of Business Innovation and Employment or by his or her authorised delegate:



Signature

Date: 19/8/20

Signed for and on behalf of **Biocell Corporation Limited** by:

N. Nair
Signature

NIDISH NAIR
Print Full Name

CEO
Print Title

Date: 11/08/2020

SCHEDULE 1 - DETAILS

1 Context

The New Zealand COVID-19 Vaccine Strategy ("**Strategy**") seeks to ensure New Zealand's access to a safe and effective vaccine, and in sufficient quantities, at the earliest possible time. The Strategy identifies a need to develop manufacturing capability and capacity in New Zealand.

Cabinet has allocated an initial \$30 million of funding to Strategic Science Investment Fund (SSIF) - Programmes to support activities under the Strategy. The Ministry intends to allocate a portion of this funding to the Recipient in order to secure access to COVID-19 vaccine manufacturing capacity, should it be required by the Strategy.

2 Appropriation and approval process (Background)

The funding for this Project is allocated from SSIF Programmes within the Vote Business, Science and Innovation Appropriation, and was approved by MBIE Deputy Chief Executive Paul Stocks on 23 June 2020.

3 Funding (*clause 2, Schedule 2*)

The maximum amount of funding available for this Project is \$2,880,000 (plus GST (if any)), such funding being a Government Grant relating to acquiring/installing and extending an asset and section CX 47 of the *Income Tax Act 2007* applies.

4 Project (*clause 2, 3, Schedule 2*)

The Recipient will upgrade one of its two facilities ("**Facility**") in Auckland to be able to produce a range of COVID-19 vaccines ("**Vaccine**"), ensure the Facility meets the Requirements (defined below) and agree to make the Facility available to partner with the Ministry (or nominee) in accordance with section 13 (Special Condition) below ("**Project**"). The Facility will meet the following requirements ("**Requirements**"):

- (a) the Facility will include two 1,000 litre bioreactors, or equivalent;
- (b) the Facility will have a filling capacity of approximately 24,000 doses per hour;
- (c) the Facility will be approved by Medsafe to manufacture Vaccine for human use. This will include it meeting the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods;
- (d) the Facility will be capable of producing Vaccine based on at least one of the following vaccine platforms and, if required by the Ministry, will be capable of producing vaccines from

the other listed platforms at additional cost (if any) to be agreed and within a reasonable time period of the Ministry's notice:

- i. live attenuated virus;
- ii. non-replicating viral vector;
- iii. replicating viral vector;
- iv. protein subunit;
- v. RNA-based;
- vi. DNA-based;
- vii. virus-like particle.

The Recipient will use its best efforts to ensure the Facility meets the Requirements by the Completion Date. The Ministry will notify the Recipient in writing when it is satisfied that the Facility meets the Requirements.

Subsequent to the Facility meeting the Requirements, the Recipient will then maintain the Facility, including so that it continues to meet the Requirements, for the period set out in clause 10 ("Maintenance").

5 Project Tasks (clause 2.5(a), Schedule 2)

Not applicable.

6 Methodology (clause 2.5(c), Schedule 2)

Not applicable.

7 Payment terms (clause 2, Schedule 2)

The Ministry will pay the Recipient the full amount of Funding (plus GST, if applicable) up to one month after the Commencement Date.

8 Standards

The Recipient must complete the Project in a manner consistent with good industry standards and in a good and efficient manner. This includes:

- (a) the Facility must meet the Requirements; and
- (b) the Recipient implementing any additional requirements requested by Medsafe.

9 Commencement Date (clause 4.1 Schedule 2)

The date the Agreement is signed by both Parties.

10 Completion Date (clause 2.5(b), Schedule 2)

31 January 2021.

11 Reporting Requirements (clause 5.1, Schedule 2)

The Recipient will provide the Ministry with progress reports ("Reports") by the last Business Day of each month and within 20 Business Days of completion of the Project.

12 Content of Report (clause 5.1, Schedule 2)

The Reports must include:

- (a) progress of the Project, including achievement of Project Tasks (if any);
- (b) a summary of expenditure to date, actual against budgeted;
- (c) plans for use of the Facility, including expected and actual demand by its customers;
- (d) plans for the next month of the Project;
- (e) any issues arising or expected to arise with the Project or this Agreement; and
- (f) any other information requested by the Ministry.

Item (c) is not required in the final report following completion of the Project.

13 Special Condition

The Recipient grants to the Ministry an option to use the Facility (including use by the Ministry's nominees) for the manufacture of Vaccine during the period of this Agreement. This option may be exercised by the Ministry by written notice to the recipient no later than five years from the date that the Ministry notifies the Recipient that the Facility meets the Requirements.

On exercise of the option, in collaboration with the Ministry (or its nominee), the Recipient will make the Facility available for the exclusive use by the Ministry (or its nominee) to produce the Vaccine as may be specified by the Ministry from the date specified by the Ministry, being no earlier than three months from the date of notice (or such earlier date as the Parties may agree). The Recipient and Ministry (or nominee) shall, as soon as practicable after the exercise of the option, execute a formal agreement on terms to be agreed for the use of the Facility. This agreement shall be on the terms acceptable to the Ministry, acting reasonably.

The Ministry shall keep the Recipient informed of its intentions to exercise the option (and any likely timeframes, so as to enable the Parties to commence any further planning, resourcing and licensing or contractual negotiations as early as possible).

Following exercise of the option, the Recipient will use its best efforts to ensure: (a) a manufacturing license is obtained from Medsafe for manufacture of the relevant Vaccine at the Facility; and (b) the necessary technology transfer for manufacture of the Vaccine, including by receiving or providing information and access relating to the Facility and entering into appropriate contractual arrangements with other parties, in order to produce the Vaccine candidates specified by the Ministry.

14 Address for Notices (clause 12.5, Schedule 2)

Ministry:	Recipient:
Ministry of Business, Innovation & Employment 15 Stout Street PO Box 1473 WELLINGTON Email address: Simon.Rae@mbie.govt.nz Attention: Simon Rae	Biocell Corporation Limited 19 Laureston Avenue, Papatoetoe, Auckland, 2025, New Zealand Email address: nidish.nair@biocellcorp.co.nz Attention: Nidish Nair

FUNDING AGREEMENT STANDARD TERMS AND CONDITIONS - SCHEDULE 2

1. Interpretation

1.1 In this Agreement, the following terms have the following meanings:

"Agreement" means this agreement, including Schedule 1 and this Schedule 2;

"Business Day" means any day not being a Saturday or Sunday or public holiday within the meaning of section 44 of the Holidays Act 2003;

"Commencement Date" has the meaning given in the Details or, if no commencement date is set out, the date of this Agreement.

"Committed" means Funding that has been spent with a third party or that the Recipient has contractually agreed to spend with a third party for the purpose of the Project in accordance with the terms of this Agreement and the Recipient, after using reasonable endeavours, is unable to secure a refund or release from its obligations to the third party in relation to that Funding;

"Completion Date" 31 January 2021;

"Confidential Information" includes all information and data (in any form) concerning the organisation, administration, operation, business, clients, finance, and methods of the Ministry, including any information provided by the Ministry under or in connection with this Agreement;

"Details" means Schedule 1;

"Funding" means the funding amount set out in the Details;

"GST" means goods and services tax within the meaning of the Goods and Services Tax Act 1985;

"Intellectual Property Rights" includes copyright and all rights conferred under statute, common law or equity in relation to inventions (including patents), registered or unregistered trade marks and designs, circuit layouts, data and databases, confidential information, know-how, and

all other rights resulting from intellectual activity;

"Parties" means the Ministry and the Recipient and their respective successors and permitted assigns;

"Project" has the meaning given in the Details;

"Project Tasks" means the project tasks (if any) set out in the Details; and

"Uncommitted Funding" means any Funding that is not Committed.

1.2 References to clauses and Schedules are to clauses and Schedules of this Agreement and references to persons include bodies corporate, unincorporated associations or partnerships.

1.3 The headings in this Agreement are for convenience only and have no legal effect.

1.4 The singular includes the plural and vice versa.

1.5 "Including" and similar words do not imply any limitation.

1.6 References to a statute include references to that statute as amended or replaced from time to time.

1.7 Monetary references are references to New Zealand currency.

1.8 If there is any conflict of meaning between the Details and Schedule 2, Schedule 2 will prevail.

2. Funding

2.1 The Ministry must pay the Funding in the manner set out in the Details. The Funding is the total amount payable by the Ministry for the Project.

2.2 Payments will be made to the credit of a bank account to be designated in writing by the Recipient.

2.3 The Funding is inclusive of all taxation except GST. The Ministry will be entitled to deduct any withholding tax required to be withheld by law from payments made to the Recipient and

will not be required to gross-up or increase any such payments in respect of such amounts withheld.

- 2.4 The Recipient must use the Funding only to carry out the Project in accordance with this Agreement.
- 2.5 In consideration of the Funding, the Recipient undertakes that it will:
- (a) use best efforts to complete each Project Task (if any) by the Completion Date set out in the Details;
 - (b) use best efforts to complete the Project (other than Maintenance) to the Ministry's satisfaction, acting reasonably, by the Completion Date;
 - (c) carry out the Project in accordance with:
 - (i) the methodology (if any) set out in the Details;
 - (ii) the best currently accepted principles and practice applicable to the field(s) of expertise relating to the Project; and
 - (iii) comply with all applicable laws, regulations, rules and professional codes of conduct or practice; and
 - (d) refund any Uncommitted Funding to the Ministry within 10 Business Days of the Completion Date.
- 2.6 Where all of the grant monies received by the Recipient to carry out the Project (including the Funding) exceeds the total cost of the Project, the Recipient must refund to the Ministry the excess amount. The Recipient is not required to refund, under this clause 2.6, any amount that exceeds the total amount of Funding.

3. Project Progress

- 3.1 If:
- (a) the Ministry is not satisfied, acting reasonably, with the progress of the Project;
 - (b) the Recipient does or omits to do something, or any matter concerning the Recipient comes to the Ministry's

attention, which, in the Ministry's opinion, acting reasonably, may damage the business or reputation of the Ministry; or

- (c) the Recipient breaches any of its obligations under this Agreement,
- the Ministry may (without limiting its other remedies):
- (d) renegotiate this Agreement with the Recipient; or
 - (e) terminate this Agreement immediately by notice to the Recipient, and clause 4.4, 4.5 and 4.6 will apply.

4. Term and Termination

- 4.1 Subject to clauses 4.2 and 4.3, this Agreement will commence on the Commencement Date and expire on the date which is five years after the date that the Ministry notifies the Recipient that the Facility meets the Requirements.
- 4.2 The Ministry may terminate this Agreement at any time by giving at least 10 Business Days' notice to the Recipient.
- 4.3 The Ministry may terminate this Agreement immediately by giving notice to the Recipient, if the Recipient:
- (a) is in breach of any of its material obligations under this Agreement and that breach is not capable of being remedied;
 - (b) fails to remedy any breach of its material obligations under this Agreement within 5 Business Days of receipt of notice of the breach from the Ministry;
 - (c) does or omits to do something, or any matter concerning the Recipient comes to the Ministry's attention, which in the Ministry's opinion may cause damage to the business or reputation of the Ministry or of the Government of New Zealand;
 - (d) has given or gives any information to the Ministry which is misleading or inaccurate in any material respect;

- (e) becomes insolvent, bankrupt or subject to any form of insolvency action or administration; or
 - (f) the Ministry has what it considers are material concerns about the Recipient's health and safety practices and, if the concerns are capable of being rectified, the Ministry has suspended the Agreement and given the Recipient the opportunity to rectify the concerns in accordance with clause 13.2.
- 4.4 Termination of this Agreement is without prejudice to the rights and obligations of the Parties accrued up to and including the date of termination.
- 4.5 On termination of this Agreement, the Ministry may (without limiting any of its other rights or remedies):
- (a) require the Recipient to provide evidence of how the Funding has been spent or Committed; and/or
 - (b) require the Recipient to refund to the Ministry:
 - (i) any of the Funding that has not been spent or Committed by the Recipient. For the purposes of this clause, Funding is committed where it has been provided or promised to a third party for the purpose of carrying out the Project and the Recipient, after using reasonable endeavours, is unable to secure a refund or release from that promise (as the case may be); or
 - (ii) the proportion of the Funding that equates to the uncompleted part of the Project, as reasonably determined by the Ministry - provided that proportion has not been Committed; and/or
 - (c) if the Recipient has breached any of its material obligations under this Agreement and such breach was within the Recipient's control, require the Recipient to return up to the full amount of Funding paid by the date of termination of the Agreement; and/or
 - (d) if the Funding has been misused, or misappropriated, by the Recipient, require the Recipient to refund all Funding paid up to the date of termination, together with interest at the rate of 10% per annum from the date the Recipient was paid the money to the date the Recipient returns the money.
- 4.6 The provisions of this Agreement relating to termination (clause 4), audit and record-keeping (clause 5.2(b), (c) and (d)), warranties (clause 6), intellectual property (clause 7), confidentiality (clause 8), and liability and insurance (clause 9) will continue after the expiry or termination of this Agreement.
- 5. Reporting Requirements and Audit**
- 5.1 The Recipient must report on the progress of the Project to the Ministry:
- (a) as set out in the Details;
 - (b) as otherwise reasonably required by the Ministry; and
 - (c) in any format and on any medium reasonably required by the Ministry.
- 5.2 The Recipient must:
- (a) maintain true and accurate records in connection with the use of the Funding and the carrying out of the Project sufficient to enable the Ministry to meet its obligations under the Public Finance Act 1989 and retain such records for at least 7 years after termination or expiry of this Agreement;
 - (b) permit the Ministry, at the Ministry's expense, to inspect or audit (using an auditor nominated by the Ministry), from time to time until 7 years after termination or expiry of this Agreement, all records relevant to this Agreement;
 - (c) allow the Ministry reasonable access to the Recipient's premises or other premises where the Project is being carried out; and

- (d) appoint a reputable firm of chartered accountants as auditors to audit its financial statements in relation to the use of the Funding.
- 5.3 The Ministry may appoint an independent auditor/expert to audit the Facility on design and capability, including its compliance with the Requirements. The Recipient will assist the Ministry in a timely manner with any audit/review conducted and will ensure its personnel also assist the Ministry.
- 6. Warranties**
- 6.1 Each Party warrants to the other Party that it has full power and authority to enter into and perform its obligations under this Agreement which, when executed, will constitute binding obligations on it in accordance with this Agreement's terms.
- 6.2 The Recipient warrants that:
- (a) it is not insolvent or bankrupt and no action has been taken to initiate any form of insolvency administration in relation to the Recipient;
 - (b) all information provided by it to the Ministry in connection with this Agreement was, at the time it was provided, true, complete and accurate in all material respects; and
 - (c) it is not aware of any material information that has not been disclosed to the Ministry which may, if disclosed, materially adversely affect the decision of the Ministry whether to provide the Funding.
- 7. Intellectual Property**
- 7.1 All Intellectual Property Rights in the reports provided under clause 5.1 will be owned by the Ministry from the date the reports are created or developed.
- 7.2 All intellectual property produced by the Recipient or its employees or contractors in relation to the Project is, on creation, jointly owned by the Ministry and the Recipient. Each Party may use (which includes modifying, developing, assigning, or licensing) such intellectual property without obtaining the prior consent of the other Party. On request, the Recipient must provide to the Ministry such intellectual property in any format, and on any medium, reasonably requested by the Ministry.
- 7.3 The Recipient must ensure that material created or developed in connection with the Project does not infringe the Intellectual Property Rights of any person.
- 8. Confidentiality**
- 8.1 The Recipient must:
- (a) keep the Confidential Information confidential at all times;
 - (b) not disclose any Confidential Information to any person other than its employees or contractors to whom disclosure is necessary for purposes of the Project or this Agreement;
 - (c) effect and maintain adequate security measures to safeguard the Confidential Information from access or use by unauthorised persons; and
 - (d) ensure that any employees or contractors to whom it discloses the Confidential information are aware of, and comply with, the provisions of this clause 8.
- 8.2 The obligations of confidentiality in clause 8.1 do not apply to any disclosure of Confidential Information:
- (a) to the extent that such disclosure is necessary for the purposes of completing the Project;
 - (b) required by law; or
 - (c) where the information has become public other than through a breach of the obligation of confidentiality in this clause 8 by the Recipient, or its employees or contractors, or was disclosed to a Party on a non-confidential basis by a third party.
- 8.3 The Recipient must obtain the Ministry's prior written agreement over the form and content of any public statement made by the Recipient relating to this Agreement, the Funding, or the Project.

9. Liability and Insurance

- 9.1 The Ministry is not liable for any loss of profit, loss of revenue or other indirect, consequential or incidental loss or damage arising under or in connection with this Agreement.
- 9.2 The maximum liability of the Ministry under or in connection with this Agreement whether arising in contract, tort (including negligence) or otherwise is the total amount which would be payable under this Agreement if the Project had been carried out in accordance with this Agreement.
- 9.3 The Recipient (including its employees, agents, and contractors, if any) is not an employee, agent or partner of the Ministry or of the Chief Executive of the Ministry. At no time will the Ministry have any liability to meet any of the Recipient's obligations under the Health and Safety at Work Act 2015 or to pay to the Recipient:
- (a) holiday pay, sick pay or any other payment under the Holidays Act 2003; or
 - (b) redundancy or any other form of severance pay; or
 - (c) taxes or levies, including any levies under the Accident Compensation Act 2001.
- 9.4 The Recipient indemnifies the Ministry against any claim, liability, loss or expense (including legal fees on a solicitor own client basis) ("loss") brought or threatened against, or incurred by the Ministry, arising from or in connection with a breach of this Agreement by the Recipient or the Project, or from the negligence or wilful misconduct of the Recipient, its employees or contractors.
- 9.5 Where the Recipient is a trustee, the Ministry acknowledges that the Recipient has entered into this Agreement as a trustee of the trust named in Schedule 1 in an independent capacity without any interest in any of the assets of the trust other than as trustee. Except where the Recipient acts fraudulently, the Recipient

is liable under this Agreement only to the extent of the value of the assets of the trust available to meet the Recipient's liability, plus any amount by which the value of those assets has been diminished by any breach of trust caused by the Recipient's wilful default or dishonesty.

- 9.6 The Recipient must effect and maintain for the term of this Agreement:
- (a) adequate insurance to cover standard commercial risks; and
 - (b) other insurance reasonably required by the Ministry.

The Recipient must, upon request by the Ministry, provide the Ministry with evidence of its compliance with this clause.

10. Dispute Resolution

- 10.1 The Parties will attempt to resolve any dispute or difference that may arise under or in connection with this Agreement amicably and in good faith, referring the dispute to the Parties' senior managers for resolution if necessary.
- 10.2 If the Parties' senior managers are unable to resolve the dispute within 10 Business Days of it being referred to them, the Parties will refer the dispute to mediation or another form of alternative dispute resolution agreed between the Parties.
- 10.3 If a dispute is referred to mediation, the mediation will be conducted by a single mediator appointed by the Parties (or if they cannot agree, appointed by the Chair of Resolution Institute) and on the terms of the Resolution Institute standard mediation agreement (unless the Parties agree otherwise). The Parties will pay their own costs relating to any mediation or other form of alternative dispute resolution (unless they agree otherwise).
- 10.4 The Parties must continue to perform their obligations under this Agreement as far as possible as if no dispute had arisen pending final resolution of the dispute.
- 10.5 Nothing in this clause 10 precludes either Party from taking immediate steps to seek urgent relief before a New Zealand Court.

11. Force Majeure

11.1 Neither Party will be liable to the other for any failure to perform its obligations under this Agreement by reason of any cause or circumstance beyond the Party's reasonable control including, acts of God, communication line failures, power failures, riots, strikes, lock-outs, labour disputes, fires, war, flood, earthquake or other disaster, or governmental action or decree after the date of this Agreement ("Force Majeure Event"). The Party affected must:

- (a) notify the other Party as soon as practicable after the Force Majeure Event occurs and provide full information concerning the Force Majeure Event including an estimate of the time likely to be required to overcome it;
- (b) use its best endeavours to overcome the Force Majeure Event; and
- (c) continue to perform its obligations as far as practicable.

12. General

12.1 A waiver by either Party of any rights arising from any breach of any term of this Agreement will not be a continuing waiver of any other rights arising from any other breaches of the same or other terms or conditions of this Agreement. No failure or delay on the part of either Party in the exercise of any right or remedy in this Agreement will operate as a waiver. No single or partial exercise of any such right or remedy will preclude any other or further exercise of that or any other right or remedy.

12.2 Assignment:

- (a) The Recipient must not assign, delegate, subcontract or transfer any or all of its rights and obligations under this Agreement. The Recipient remains liable for performance of its obligations under this Agreement despite any approved subcontracting or assignment.
- (b) If the Recipient is a company, any transfer of shares, or other

arrangement affecting the Recipient or its holding company which results in a change in the effective control of the Recipient is deemed to be an assignment subject to clause 12.2(a).

12.3 This Agreement may only be varied by agreement in writing signed by the Parties.

12.4 If any part or provision of this Agreement is invalid, unenforceable or in conflict with the law, the invalid or unenforceable part or provision will be replaced with a provision which, as far as possible, accomplishes the original purpose of the part or provision. The remainder of the Agreement will be binding on the Parties.

12.5 Any notice to be given under this Agreement must be in writing and hand delivered or sent by email or registered post to the Parties' respective email address, postal address as set out in the Details. A notice is deemed to be received:

- (a) if personally delivered when delivered; or
- (b) if posted, three Business Days after posting;
- (c) if sent by email, at the time the email enters the Recipient's information system as evidenced by a delivery receipt requested by the sender and it is not returned undelivered or as an error,

provided that any notice received after 5pm or on a day which is not a Business Day shall be deemed not to have been received until the next Business Day.

12.6 This Agreement sets out the entire agreement and understanding of the Parties and supersedes all prior oral or written agreements, understandings or arrangements relating to its subject matter.

12.7 This Agreement may be signed in any number of counterparts (including emailed copies) and provided that each Party has signed a counterpart, the counterparts, when taken together, will constitute a binding and enforceable agreement between the Parties.

12.8 This Agreement will be governed by and construed in accordance with the laws of New Zealand.

13. Health and Safety

13.1 The Recipient must promptly notify the Ministry of any notifiable events under the Health and Safety at Work Act 2015 that occur in the performance of the Agreement or that have the potential to impact the performance of the Agreement.

13.2 The Ministry may suspend this Agreement immediately by giving written notice to the Recipient if the Ministry has what it

considers are material concerns about the Recipient's health and safety practices. Upon notice of the suspension, the Recipient will have an opportunity to rectify the health and safety issue(s) specified in the notice to the satisfaction of the Ministry. If the health and safety issue(s) specified in the notice are not rectified to the satisfaction of the Ministry within 20 Business Days, the Ministry may terminate the Agreement immediately under clause 4.3.

[REDACTED]

From: Simon Rae
Sent: Friday, 28 August 2020 4:20 PM
To: Nidish Nair
Subject: Equipment lead times [UNCLASSIFIED]

Hi Nidish,

A quick note to follow up something you said on the phone the other day.

You mentioned something about lead times for equipment, 9(2)(ba)(i) [REDACTED]
[REDACTED] I was wondering whether you had started having conversations with suppliers yet, and whether you had any ideas of availability (primarily at the 1000L size). If lead times are particularly difficult we would be interested in talking through what we might do to help. I am presuming the equipment required is not able to be custom fabricated to specifications either?

Simon

Simon Rae
POLICY AND STRATEGY
New Zealand COVID-19 Vaccine Task Force
Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a) [REDACTED]
15 Stout Street, PO Box 5762, Wellington, 6145

From: Simon Rae
Sent: Wednesday, 16 September 2020 12:19 PM
To: Max Shepherd
Cc: deb@coalspud.co.nz; Justine Daw
Subject: RE: MBIE and Biocell [UNCLASSIFIED]

Hi Max,

Yes, that would be useful. 4pm this afternoon will work well for me. Maybe call my mobile 9(2)(a).

I will invite my colleague Justine Daw along to the call – Justine is leading our science and manufacturing work as part of the Task Force.

Simon

From: Max Shepherd <max.shepherd@biocellcorp.co.nz>
Sent: Tuesday, 15 September 2020 4:40 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Cc: deb@coalspud.co.nz
Subject: MBIE and Biocell

Hello Simon,

There have been some developments regarding the contract between MBIE and Biocell that I wish to discuss with you. Would you be available to take a call at 4pm tomorrow? If this time does not suit would you please provide suitable times.

Regards

Max Shepherd

Director and Founder

Biocell Corporation Ltd.

From: Zachary Clarke
Sent: Tuesday, 20 October 2020 5:49 PM
To: William Rolleston
Cc: Simon Rae
Subject: RE: Reference to information provided by SPS about costs of a vaccine facility [UNCLASSIFIED]

Hi William,

See below for the paragraphs that mention SPS in the decision memo. SPS is not mentioned directly or indirectly in any of the other documents.

We have had some initial engagement with the New Zealand pharmaceutical and biotechnology sector to determine New Zealand's human vaccine manufacturing potential, and to identify where government support may be needed. Through this engagement, we have identified two obvious candidates for investment in the short term, BioCell and South Pacific Sera. While we will not have time to complete an exhaustive analysis of the sector before BioCell's deadline, other credible manufacturers that we are aware of are largely involved in manufacturing animal vaccines, and it will take significant time and investment to transition this capability to manufacture human vaccines.

Of the two manufacturers, BioCell is closest to producing a COVID-19 vaccine because it already has a suitable building that can be dedicated to this manufacturing, purchased from another biotechnology company earlier this year, and they have already made some investments in order to manufacture COVID-19 vaccine trial material for a UK company.

South Pacific Sera (SPS), has expressed an interest in setting itself up to manufacture COVID-19 vaccines, but has indicated that it would need to build an additional building on its current manufacturing site in order to do so. We have prioritised the BioCell investment as an investment to upgrade SPS's capability will cost a significantly greater amount and take longer to complete. Informally SPS has indicated to us that it would expect the cost for a facility to be approximately 9(2)(ba)(i) [REDACTED]

Cheers,
Zac

From: Simon Rae
Sent: Tuesday, 20 October 2020 5:29 p.m.
To: William Rolleston
Cc: Zachary Clarke
Subject: RE: Reference to information provided by SPS about costs of a vaccine facility [UNCLASSIFIED]

Thanks William. Zac will forward you the relevant section.

Simon

From: William Rolleston <william.rolleston@southpacificsera.co.nz>
Sent: Tuesday, 20 October 2020 3:59 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Subject: RE: Reference to information provided by SPS about costs of a vaccine facility [UNCLASSIFIED]

Hello Simon

Yes the information we have supplied to you 9(2)(ba)(i) are commercial in confidence as it relates to 9(2)(ba)(i) and could be disruptive to our current customer relationships and arrangements (including exports), could compromise current commercial negotiations as well as provide competitors with key strategic information compromising our competitive position. We also request our name is redacted for the same reason. I would add that since we are the leading manufacturers in this space a careful and comprehensive redaction will be required.

Please note that we have made no application to you for funds but have only provided estimates in response to your questions. We have however offered our services and capabilities to you which are already GMP/PC2.

Please forward me a copy of the redacted release so that our lawyers may have the opportunity to challenge any disclosure.

Regards
William

Dr WBR Rolleston
Production Director, South Pacific Sera Ltd
PO Box 2117, Washdyke, Timaru 7941
26 Kennels Road, Timaru 7974
New Zealand
9(2)(a)
www.southpacificsera.co.nz

From: Simon Rae [mailto:Simon.Rae@mbie.govt.nz]
Sent: Tuesday, 20 October 2020 2:51 PM
To: William Rolleston
Subject: Reference to information provided by SPS about costs of a vaccine facility [UNCLASSIFIED]

Kia ora William,

We've received an Official Information Act covering MBIE's decision to invest \$2.88 million to upgrade BioCell's facilities. One of the documents covered by the request includes informal estimates you provided to me on the timing and costs of building a facility to undertake human vaccine manufacture at SPS 9(2)(ba)(i)

Would you have any concerns if we released those figures as part of the request, or do you regard them as having been provided in confidence? If so, could you please let me know by **12pm Wednesday this week** (we're required to release the information by the end of that day). We may be able to redact the information under the OIA but if we did it would be useful to have a brief description from you (2-3 sentences max) on the potential negative consequences of releasing the information.

Ngā mihi,

Simon

Simon Rae
POLICY AND STRATEGY
New Zealand COVID-19 Vaccine Task Force
Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)

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From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Friday, 30 October 2020 4:32 PM
To: Zachary Clarke
Subject: RE: Official Information Act request for information on the MBIE/BioCell investment decision
Attachments: Update report 1.docx

Hello Zachary,

I trust you are keeping well and that you were able to handle the OIA request appropriately.

Please see attached a brief progress report as you requested.

Have a great weekend.

Cheers,

Nidish

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Wednesday, 21 October 2020 3:45 PM
To: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Cc: becshepherd10@gmail.com
Subject: Fw: Official Information Act request for information on the MBIE/BioCell investment decision

Kia ora Zachary

Thank you for your email notifying us that there has been a request for information pursuant to the OIA.

We have considered the documents and the proposed decision memo paragraph and we make the following comments:

- In relation to the 16 June application, we have attached a copy that has some sections highlighted for redaction. Those sections have been highlighted on the basis of commercially sensitive information and some information that is subject to an obligation of confidence with another commercial party.
- In relation to the Funding Agreement signed 19 August could you please come back to us as to whether this agreement can be withheld on the basis that it is a confidential contract signed between two parties and contains commercially sensitive information.
- In relation to your proposed paragraph in the decision memo can you please amend the final sentence to the following:
"Biocell is requesting a decision by 23 June because there is a call with the directors scheduled to discuss potential projects."

Please let me know if there is anything you would like to discuss.

Kind regards,
Nidish

From: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Sent: Thursday, 15 October 2020 4:09 PM
To: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Subject: Official Information Act request for information on the MBIE/BioCell investment decision

Kia ora Nidish,

OIA request

We've received the following Official Information Act request from a journalist:

I request any information received by MBIE, as part of the Covid-19 Vaccine Strategy Taskforce, from the company BioCell which resulted in BioCell receiving money to upgrade its Auckland facilities. This should be including but not limited to its funding application and any subsequent correspondence.

I've attached the documents that are in the scope of the request. Could your team please review the documents, and let me know if they contain anything commercially sensitive that you would like us to withhold. Under the OIA, we're only able to withhold information if negative consequences would likely result from the release. If your team would like us to withhold information, could you therefore please give me a brief description of why you think the redaction would be necessary (e.g. releasing this information would harm BioCell's commercial position through providing competitors with access to a crucial trade secret). We will also withhold your personal mobile number to protect your privacy.

We've also been OIA'ed for our decision memos on the investment. Would any harm result from releasing the following paragraph in one of the memos?

"BioCell has advised us that they are seeking urgent funding because if this proposal is unsuccessful they will need to reconfigure the facility to accept an offer from a different commercial project (producing trial material for a non-COVID) vaccine. BioCell's deadline for this decision is 23 June, as that is the last date they are able to accept the offer from the separate project"

Reporting

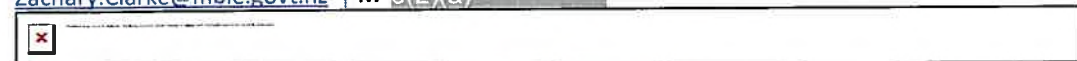
Finally, in reviewing the our contract I've realised we've forgotten to follow up on the contract's requirement for monthly progress reports from BioCell. The first report is due this month, so we please ask for a short written progress update by **Friday 30 October**? We don't require any specific report templates, so an email or word doc covering relevant progress would be fine.

Ngā mihi nui,
Zachary

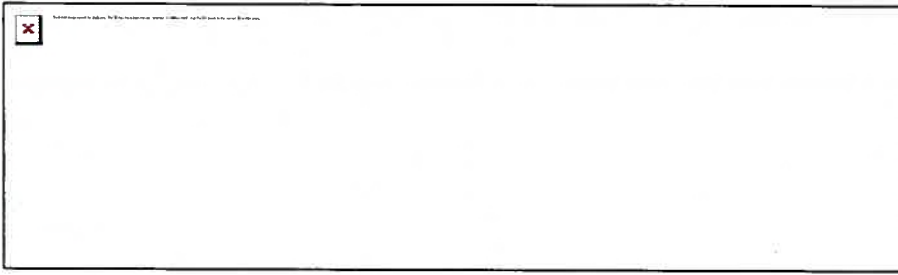
Zachary Clarke

Policy Advisor | COVID-19 Vaccine Strategy / International Science Partnerships
Science, Innovation & International | Labour Science & Enterprise Group

Zachary.Clarke@mbie.govt.nz | M 9(2)(a)



MINISTRY OF BUSINESS INNOVATION & EMPLOYMENT / HIKINA WHAKATUTUKI
15 Stout Street , PO Box 1473, Wellington | www.mbie.govt.nz | NZBN 9429000106078



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Update report 1

30 October 2020

Hello Zachary,

I am pleased to report that we are making good progress with identifying and reviewing suppliers from around to world to ensure that the equipment we are purchasing meets the following four criteria:

1. High quality
2. Meets cGMP guidelines
3. Provides best value for money
4. Short lead time

We have so far identified and are in the process of completing the review of the following suppliers:

Supplier	Country of Origin
9(2)(ba)(i)	

We are hoping to finalise orders in the coming weeks and look forward to updating you on our progress next month.

Cheers,

Nidish Nair

From: Simon Rae
Sent: Thursday, 12 November 2020 1:19 PM
To: William Rolleston
Cc: Peter Crabtree
Subject: Re: Pfizer vaccine

Hi William,

Thanks for your email. The Ministry of Health have been actively procuring supplies and equipment required for delivery of the vaccines on our target list. Our understanding from them is that we are well-placed for now, but your offer is still welcome in case that situation changes in future.

Simon

On 11/11/2020, at 11:11 AM, William Rolleston <william.rolleston@southpacificsera.co.nz> wrote:

Hi Simon

Can we provide any assistance with the Pfizer vaccine?

We manufacture our own liquid nitrogen on site in Timaru and have some low temperature storage space for vials if this is helpful.


We may also be able to get access to large liquid nitrogen vial storage/transport vessels.

John and I have discussed this and would consider supplying some of this in kind to enable you to get going as soon as you need to.

Regards
William

Dr WBR Rolleston
Production Director, South Pacific Sera Ltd
PO Box 2117, Washdyke, Timaru 7941
26 Kennels Road, Timaru 7974
New Zealand

www.southpacificsera.co.nz



From: Simon Rae
Sent: Friday, 13 November 2020 4:23 PM
To: William Rolleston
Subject: Media inquiry

Hi William,

We've had a media inquiry from Bevan Hurley from stuff about our manufacturing investments. I'd be interested in a read out of what you've said to him if that was OK.

From our perspective, and just to be clear, we are still open to conversations with you about future manufacturing capacity for pandemic resilience.

Regards,

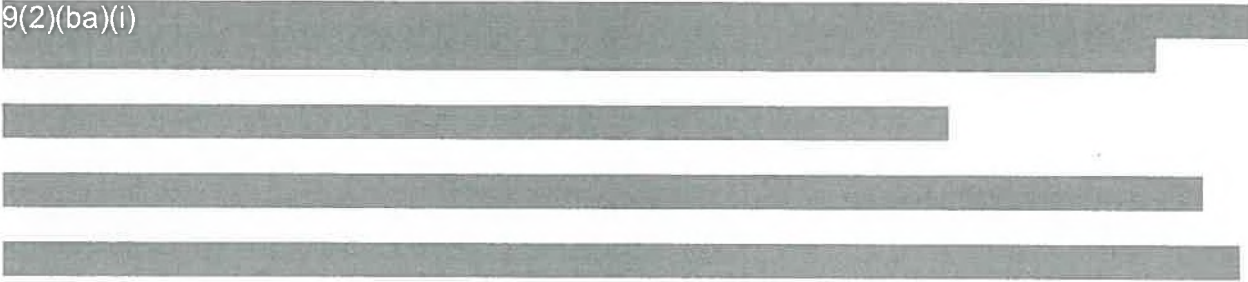
Simon

From: William Rolleston <william.rolleston@southpacificsera.co.nz>
Sent: Monday, 16 November 2020 11:13 AM
To: Simon Rae
Cc: Peter Crabtree
Subject: RE: South Pacific Sera Ltd. [UNCLASSIFIED]

Thanks Simon, I appreciate that.

Do you have time to talk today please?

9(2)(ba)(i)



Regards
William

Dr WBR Rolleston
Production Director, South Pacific Sera Ltd
PO Box 2117, Washdyke, Timaru 7941
26 Kennels Road, Timaru 7974
New Zealand
9(2)(a)
www.southpacificsera.co.nz

From: Simon Rae [mailto:Simon.Rae@mbie.govt.nz]
Sent: Monday, 16 November 2020 10:27 AM
To: William Rolleston
Cc: Peter Crabtree
Subject: RE: South Pacific Sera Ltd. [UNCLASSIFIED]

Thanks William. Yes we were aware of this distinction, and we have found the Medsafe list very useful in understanding the capabilities of various organisations, and the differences in licenses they hold.

Simon

From: William Rolleston <william.rolleston@southpacificsera.co.nz>
Sent: Sunday, 15 November 2020 12:26 PM
To: Simon Rae <Simon.Rae@mbie.govt.nz>
Cc: Peter Crabtree <Peter.Crabtree@mbie.govt.nz>
Subject: South Pacific Sera Ltd.

Dear Simon

I read the article on Biocell in the Sunday Star Times this morning and note that the journalist said:

“...South Pacific Sera (SPS), a Timaru-based animal cell culture business which unlike Biocell is Medsafe-approved to make animal vaccines.”

If this information came from MBIE, this is the advice that MBIE has or this is the basis on which MBIE is making its decisions then could I offer a correction.

Both Biocell and SPS are licenced to manufacture certain veterinary medicines by the ACVM.

However only SPS has a licence to manufacture sterile human medicines from Medsafe.

If you missed this subtle but important point in our initial conversation then I apologise but please be clear that we have registration from Medsafe which can be found [here](#).


I hope that clears up any misunderstanding.

Regards
William

Dr WBR Rolleston
Production Director, South Pacific Sera Ltd
PO Box 2117, Washdyke, Timaru 7941
26 Kennels Road, Timaru 7974
New Zealand
b(2)(a)
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From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Monday, 30 November 2020 7:11 PM
To: Zachary Clarke
Subject: brief update 2
Attachments: Update report 2.docx

Hello Zachary,

I trust you and the team are doing well.

Please find attached the second brief update report.

Cheers,

Nidish

Update report 2

30 November 2020

Hello Zachary,

We continue to make good progress with identifying and reviewing critical scientific equipment suppliers across Europe and USA.

Reviews completed so far:

Supplier	Country of Origin
9(2)(ba)(i)	

Major purchases made:

We have recently concluded the purchase of a bioreactor 9(2)(ba)(i) and an in-line high speed centrifuge 9(2)(ba)(i)

Upcoming purchases:

Over the next month we will be finalising another bioreactor supplier and the supplier for an automated sterile vial filling line.

The suppliers we are currently reviewing are:

Supplier	Country of Origin
9(2)(ba)(i)	

We will continue to keep you posted on our progress.

Cheers,

Nidish

From: Simon Rae
Sent: Thursday, 3 December 2020 12:23 PM
To: Nidish Nair; Max Shepherd
Cc: Karl Ferguson
Subject: Possible visit to BioCell, Thursday 17 December [UNCLASSIFIED]

Nidish, Max,

On 17 December the Prime Minister and Minister Woods are planning to undertake some publicity connected to the vaccine strategy. Details are TBC but we have been asked to urgently provide advice about visit opportunities that would support the Government's plans to purchase and roll-out COVID-19 vaccines.

We would be looking for:

- A suitable space that could host the PM/Ministers, advisers and a reasonable media contingent
- PM/Minister would make an announcement and hold a press briefing
- Following the briefing, we would expect the PM/Minister would have the opportunity to: tour the facility and be briefed on some vaccine related work
- The planned activity would need to be 'media friendly' obviously

Having visited BioCell, I'm conscious there may be limitations in terms of the spaces available for this sort of thing, and constraints on visits depending on what work is underway at the time.

Karl Ferguson is our lead on comms for the vaccine strategy, and he will follow up directly. If you want to call him, his number is

9(2)(a)

Regards,

Simon

Simon Rae

POLICY AND STRATEGY
New Zealand COVID-19 Vaccine Task Force
Science, Innovation and International Policy
Ministry of Business, Innovation & Employment

simon.rae@mbie.govt.nz | Mobile: 9(2)(a)
15 Stout Street, PO Box 5762, Wellington, 6145



From: Zachary Clarke
Sent: Friday, 29 January 2021 5:57 PM
To: Nidish Nair
Subject: RE: brief update 3 [UNCLASSIFIED]

Thanks Nidish, much appreciated.

Have a great weekend!

Zach

From: Nidish Nair <nidish.nair@biocellcorp.co.nz>
Sent: Friday, 29 January 2021 4:49 PM
To: Zachary Clarke <Zachary.Clarke@mbie.govt.nz>
Subject: brief update 3

Hello Zachary,

I trust you have had a pleasant break over Christmas.

Please find attached the next update report.

Cheers,

Nidish





Update report 3 (December 20, January 21)

29 January 2021

Hello Zachary,

I am pleased to report that we have made excellent progress with finalising the suppliers, defining specifications, finalising design drawings and committing all of the available funding money.

The equipment we have finalised is of exceptional quality and are from established suppliers around the world.

Most of the high-tech equipment including spare part components are manufactured and supplied from the U.K, Europe and the USA. At a time when suppliers in Europe and in the US are reeling under lockdowns/various restrictions which have drastically affected global supply chains and lead times, it is challenging to get everything required in a short space of time.

In some cases, the same suppliers are supplying equipment to other global pharma companies. So, while Biocell is firmly in the queue, our delivery dates have not been firmed up due to high demand. However, we have been advised that most of the items will be shipped by early-mid 2021.

One of the most critical equipment is the sterile filling machine from 9(2)(ba)(i) who supplies machines worldwide including the companies that are filling Pfizer/Biontech and Moderna vaccines.

The 9(2)(ba)(i) filling machine we have ordered has the ability to fill more than 24,000 doses an hour.

We have also commissioned 9(2)(ba)(i), who is one of the largest engineering companies in the world that specialises in pharmaceutical equipment to supply a 5,000L bioreactor.

We will continue to keep you posted on our progress.

Cheers,

Nidish

